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2018-03

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Bonaros , N , Kofler , M , Frank , D , Cocchieri , R , Jagielak , D , Aiello , M , Lapeze , J ,  
Laine , M , Chocron , S , Muir , D , Eichinger , W , Thielmann , M , Labrousse , L , Bapat , V ,  
Rein , K A , Verhoye , J-P , Gerosa , G , Baumbach , H , Deutsch , C , Bramlage , P ,  
Thoenes , M & Romano , M 2018 , ' Balloon-expandable transaortic transcatheter aortic  
valve implantation with or without predilation ' , Journal of Thoracic and Cardiovascular  
Surgery , vol. 155 , no. 3 , pp. 915-923 . <https://doi.org/10.1016/j.jtcvs.2017.10.071>

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<http://hdl.handle.net/10138/300990>

<https://doi.org/10.1016/j.jtcvs.2017.10.071>

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# Balloon-expandable transaortic transcatheter aortic valve implantation with or without predilation

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## ABSTRACT

**Objective:** It has been reported that balloon aortic valvuloplasty immediately before transfemoral or transapical transcatheter aortic valve implantation has mostly little to no clinical value. We aimed to provide data on the need for balloon aortic valvuloplasty in patients undergoing transaortic transcatheter aortic valve implantation.

**Methods:** Patients undergoing transaortic transcatheter aortic valve implantation with the Edwards SAPIEN XT (Nyon, Switzerland) or 3 transcatheter heart valve were prospectively included at 18 sites across Europe. In the present analysis, we compare the periprocedural and 30-day outcomes of patients undergoing conventional (balloon aortic valvuloplasty) versus direct (balloon aortic valvuloplasty) transaortic transcatheter aortic valve implantation.

**Results:** Of the 300 patients enrolled, 222 underwent conventional and 78 underwent direct transaortic transcatheter aortic valve implantation. Peak and mean transvalvular gradients were improved in both groups with no significant difference between groups. Procedural duration, contrast agent volume, and requirement for postdilation were also comparable. A trend toward fewer periprocedural complications was evident in the direct group (3.9% vs 11.3%;  $P = .053$ ), with significantly lower rates of permanent pacemaker implantation (0% vs 5.0%;  $P = .034$ ). Balloon aortic valvuloplasty omission had no significant effect on any of the 30-day safety and efficacy outcomes, including Valve Academic Research Consortium-2 composite end points (early safety events: 22.7% vs 17.4%, odds ratio, 1.17, 95% confidence interval, 0.53-2.62; clinical efficacy events: 20.5% vs 18.7%, odds ratio, 1.14, 95% confidence interval, 0.51-2.55).

Periprocedural complications and procedural outcomes in conventional versus direct TAO-TAVI.

### Central Message

Predilation in transaortic TAVI procedures using an Edwards SAPIEN (Nyon, Switzerland) balloon-expandable valve seems to have little clinical value for many patients and may result in a higher rate of PPI.

### Perspective

Although BAV predilation in TA- and TF-TAVI seems to be of little clinical value, evidence for this in TAO-TAVI is lacking. Our real-world data reveal that many findings from TA and TF studies also apply to TAO-TAVI and suggest that omission of predilation may reduce periprocedural PPI. This is valuable knowledge for informing surgical decisions and adds to the limited data on TAO-TAVI.

See Editorial Commentary page 924.

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**Key Words:** aortic stenosis, balloon aortic valvuloplasty, predilation, transaortic, transcatheter aortic valve implantation